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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,229	03/24/2000	Akira Kawakami	P17156-00004	1735

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EXAMINER
RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 12/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/534,229	KAWAKAMI ET AL.	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-20,23 and 24* is/are pending in the application.

4a) Of the above claim(s) *19 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12, 13, 15, 17, 18, 23-24* is/are rejected.

7)☒ Claim(s) *14 and 16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 12-20, 23-24 are still at issue and are present for examination. Claims 12-18 and 23-24 are now under consideration. Claims 19-22 remain withdrawn from consideration as being drawn to non-elected invention.

Election/Restrictions

Applicants request to rejoin claims 19 and 20 with group I is acknowledged. However, amended claim 19 and claim 20 remain withdrawn from consideration at this time as claims 12-18, 23-24 remain non-allowable. Examiner will consider rejoining claims 19-20 when claims 12-18 an 23-24 are in condition for allowance. Until such time the claims continue to be withdrawn from consideration.

Applicants' amendments and arguments filed on 10-18-02, paper No. 21, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

Claim 14 is objected to because of the following informalities: Claim 14 refers to an amino acid sequence through a figure number. The actual SEQ ID NO: has been omitted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 15, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13, 15 and 17 are rejected as indefinite because each of the claim recites the phrase "encodes an amino acid sequence that is .....% identical with ..... chitinase cDNA". It is well understood in the art that cDNAs comprise only nucleotides, they do not comprise amino acids. Applicants are comparing the encoded amino acid sequences to a nucleotide sequence, a cDNA, rendering the claim unclear or indefinite. It appears that applicants have misread or misunderstood Examiner's previous suggestion.

Claims 13, 15, and 17 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13, 15 and 17 are also rejected as indefinite because these claims refer to a nucleotide sequence/amino acid sequence without reciting the corresponding SEQ ID NO. Without a specific SEQ ID NO, it would be impossible for the Examiner to search the limitations of these claims especially when claiming sequence similarity (such as 98% identity with a barley chitinase as in claim 13, 68% identity to a rye-chitinase as in claim 15 or the 95% identity to a spring wheat chitinase in claim 17) with another nucleotide sequence/amino acid sequence just by providing the total number of nucleotides. Furthermore, the claims are also indefinite because these claims compare the claimed cDNA sequence with the

cDNA for barley, rye and spring-wheat chitinases without providing SEQ ID NO for those respective cDNA sequences. Without providing the specific barley, rye or spring-wheat chitinase cDNAs it is not clear to the Examiner whether applicants compare the sequence with specific barley, rye or spring-wheat chitinase cDNAs or with any barley, rye or spring-wheat chitinase cDNAs. Examiner has broadly interpreted the latter as the intent of the applicants.

In response to the previous Office action, applicants have traversed the above rejection arguing that these claims do not require specific sequences which are instead listed in claims 14, 16 and 18 and that they do not believe it is necessary to amend these claims to include sequences at this time. Examiner respectfully disagrees with such a conclusion. As explained in the above rejection, without a SEQ ID NO for either the winter wheat chitinases that they are claiming or respective SEQ ID NO for the barley, rye and spring-wheat chitinases, it would be impossible for the Examiner to search and determine the per cent sequence identities that applicants are claiming. It should be noted that many species contain multiple distinct chitinase genes. As each gene has a distinct sequence the per cent identity to each barley, rye or spring wheat chitinase gene will be different. One cannot determine the scope of the claimed wheat genes without knowing which specific gene sequence it must have 98% amino acid sequence identity to. Therefore Examiner continues to maintain the above rejection until SEQ ID NOs are provided.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 is drawn to a winter wheat chitinase cDNA corresponding to a

polynucleotide sequence listed as SEQ ID NO:3 in figure 3. First of all SEQ ID NO:3 is not a polynucleotide sequence but an amino acid sequence. Therefore, it is unclear to the Examiner whether applicants are claiming a polynucleotide or a polypeptide sequence. Next, the claim recites the phrase "corresponding to a". It is not clear to the Examiner as to what applicants mean by the above phrase. A perusal of the specification does not provide a definition for the above phrase thus rendering the claim unclear or indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-13, 15, 17, 23-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides(cDNA) isolated from winter wheat, with SEQ ID NO:6, 7, or 8, encoding a chitinase enzyme with amino acid sequence as depicted in SEQ ID NO:1, 2 or 3 respectively, does not reasonably provide enablement for any other winter wheat polynucleotides (cDNAs), including recombinants, mutants and variants encoding a chitinase enzyme or any polynucleotide that is either 771, 972, or 960 nucleotides long encoding a chitinase enzyme comprising 250, 323 or 319 amino acids respectively having 98%, 68% or 95% amino acid sequence identity to barley, rye and spring wheat chitinase enzymes respectively. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 12-13, 15, 17, 23-24 are so broad as to encompass any polynucleotide isolated from any variety or species of winter wheat (wild or domesticated crop) including recombinants, variants and mutants. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of cDNAs broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. Furthermore while only few species of wheat have been domesticated by man and grown as crops there could be several wild strains of wheat that are hitherto unknown to man. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only three winter wheat chitinases.

While DNA isolation techniques, recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and in the case of recombinant and mutants, the positions of

amino acids within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all or any cDNA encoding a chitinase of any variety of winter wheat, modifications and fragments thereof because the specification does not establish: (A) a rational and predictable scheme for modifying any winter wheat chitinase residues with an expectation of obtaining the desired biological function; (B) regions of the protein structure which may be modified without effecting activity; (C) the general tolerance of winter wheat chitinases to modification and extent of such tolerance; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any or all the winter wheat derived chitinase cDNAs. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of winter wheat chitinase cDNAs having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 12-13, 15, 17, 23-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules encoding a winter wheat proteins having chitinase activity at low temperatures. Also, claims 13, 15 and 17 are directed to a genus of DNA molecules having the limitations of comprising 771 nucleotides, 972 nucleotides or 960 nucleotides and encoding a chitinase enzyme that is 98% identity with barley-derived chitinase (at the amino acid level), or encoding a chitinase enzyme that is 68% identity with rye-derived chitinase (at the amino acid level) or encoding a chitinase enzyme that is 95% identity with spring wheat-derived chitinase (at the amino acid level) having the SEQ ID NO:2 or any DNA which is 95% identical to SEQ ID NO:1 or encodes a protein that is 95% identical to SEQ ID NO:2.

The specification does not contain any disclosure of the structure of all DNA sequences that encode a winter wheat chitinase enzyme active at low temperatures. The genus of DNAs that comprise these above cDNA molecules is a large variable genus with the potentiality of having many different structures (i.e. nucleotide sequences). Therefore, many structurally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only three species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Similarly, the specification does not contain any disclosure of the structure of all DNA sequences that comprise 771 nucleotides, 972 nucleotides or 960 nucleotides and encoding a chitinase enzyme or the structures of barley or rye or spring-wheat derived chitinase cDNAs. While applicants describe the length of the DNA molecules as 771 nucleotides, 972 nucleotides or 960 nucleotides they do not provide the actual sequence of the polynucleotides. The genus of DNAs that comprise these above cDNA molecules is a large variable genus with the potentiality of having many different structures. Therefore, many structurally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only three species of the claimed genus (each corresponding to the specific lengths of the DNAs mentioned above) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

In response to the previous Office action, applicants have traversed the above rejection arguing that the claimed cDNA is specifically limited to winter wheat chitinase cDNA rather than any cDNA as the Examiner previously interpreted and that the above two rejections are moot due to the new amendments to the claims. Examiner respectfully disagrees with such an argument as the amendment does not overcome the previous rejection and as the claims are still

too broad and genus of cDNA claimed have not been described in the specification. Therefore the above rejections are maintained.

Allowable Subject Matter

Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

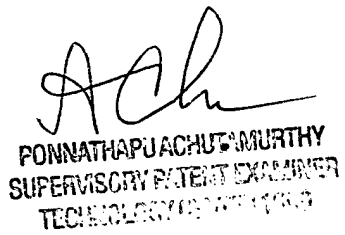
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.



Manjunath N. Rao
December 27, 2002